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REMARKS

In response to the non-final Office Action mailed October 18, 2007, the Attorney for the Assignee submits the present amendments and remarks. The Office Action rejected claims 1-9 and withdrew 10-24 from further consideration. The present amendment cancels claims 10-24 without prejudice. The Applicant reserves the right to pursue claims 10-24 in another application for patent. Accordingly, the pending claims are 1-9. The response is believed to traverse the Office Action rejections and objections, and allowance of the pending claims is kindly requested.

I. Election/Restrictions

The Applicant kindly thanks the Examiner for the withdrawal of the election requirement. The present amendment cancels claims 10-24 without prejudice, and the Applicant reserves the right to pursue claims 10-24 in another application for patent.

II. Information Disclosure Statement

The Office Action requested the Applicant to point out any particular references that the Applicant believes may be of particular relevance to the present application. In response, the Applicant identifies the following references, which were cited by a search associate in connection with a search on the subject matter of the present application:

- United States Patent Application No. 2002/0052606 to *Peter Bonutti*;
- International Patent Application No. WO 01/93770 to *P. D. and N. J. Chumas* and No. WO 02/41794 to *Neorad A/S*; and
- U.S. Patents Nos. 6,044,291 to *LAP GmbH*; 5,598,269 to *Children's Hospital Medical Centre*; 6,144,875 to *Accurary Inc.*; 6,041,249 to *Siemens Akt.*; 5,810,841 to *Minrad Inc.*; and 5,782,842 to *Daum GmbH*.

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III. Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected all of the pending claims 1-9 under 35 U.S.C. § 102(b) as being anticipated by *Kliegis et al.* (U.S. Patent No. 5,715,836). The rejection is respectfully traversed because *Kliegis* does not describe or suggest all of the elements of the claims. Specifically, *Kliegis* does not describe or suggest a method that uses a computer aided surgical navigation system (CAS) that includes "a sensor adapted to sense the position and orientation of at least one surgical reference associated with a structure to be referenced." Rather, as discussed more fully below, *Kliegis* merely discloses the use of a video camera to monitor the position the patient's body, and does not contain enabling disclosure regarding the use of a CAS system including at least one surgical reference and one sensor.

A. Summary of the Present Invention

All of the pending claims 1-9 relate to methods that include the use of a CAS system, including at least one surgical reference and a sensor, to track the position and orientation of (a) a portion of an individual's bony anatomy and skin proximate the bony anatomy; and (b) an incision device. For example, the specification states that "the reference structures have at least three ... markers or fiducials that are tracked by an infrared sensor to determine the position and orientation of the reference and thus the position and orientation of the associated instrument, implant component or other object to which the reference is attached." (*Specification*, p. 3, ll. 18-23).

One advantage of using a CAS system is the flexibility to update information regarding position in the event that a patient moves. "In some embodiments, computer functionality 18 may be adapted to update the suggested incision path and length in real time if the position or orientation of the body part 36 changes. By tracking the position and orientation of the surgical reference or references 16 associated with the bony anatomy 42 and proximate skin 44 the computer functionality 18 may adjust the suggested incision path and / or length to compensate for changes in position and / or orientation of the body part 36." (*Id.*, p. 18, ll 1-6).

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The specification discusses some known methods that use light emitters, for example, to attempt to aid the surgeon make an accurate incision. These known systems have drawbacks, however, as they "do not use the computer assisted surgical navigation system to track the progress of the surgical instrument during the surgical procedure. Consequently, if the light emitters are inadvertently misaligned, the surgeon may receive inaccurate guidance such that the incision is not performed along the desired incision path and / or length ... [T]he light emitters of these previous systems may be difficult and time consuming to set-up, properly align and otherwise prepare for the procedure. Additionally ... it may be necessary to recalibrate the entire system, increasing the time, expense and frustration associated with the procedure." (*Id.*, p. 4, l. 26 – p. 5, l. 6).

B. Summary of *Kliegis*

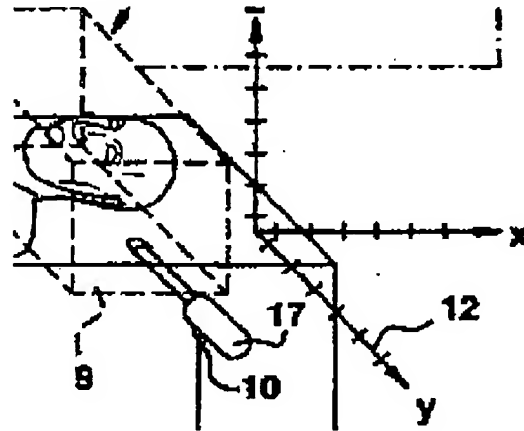
The Office Action states that *Kliegis* anticipates the claimed invention; however, the rejection is respectfully traversed because *Kliegis* does not describe or suggest all of the aspects of the claimed invention. Rather, *Kliegis* describes a method using a video camera, and does not describe a method that uses a CAS system with sensor to sense at least one surgical reference.

Kliegis describes the use of a video camera to monitor the operation site during the surgical procedure. For example, *Kliegis* states that "a further preferred embodiment of the invention brings the section surface and/or the desired image into coincidence with the actual image by recording the operation site, for example with a video camera." (*Kliegis*, 2:52-53). (See also *id.*, 3:7-12) (describing stereoscopic images of the actual operation site taken by two video cameras). *Kliegis* states that the "video image signal is compared in real time with the data record of the desired image" to perform certain calculations. (*Id.*, 2: 55-59). (See also *id.*, 6:42-47) (describing the use of "recorded images"). Finally, *Kliegis* describes the use of a video camera to monitor the movement of the incision path. "The monitoring of the incision path can be still further improved by recording continuously that the operation site

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visible through the eyepiece of the surgical microscope (4) using a video camera (3)." (*Id.*, 6:40-43).

Kliegis describes the use of a coordinate system to position the operation site; however, the coordinate system does not describe or suggest a CAS system including a sensor and a surgical reference. *Kliegis* states that "the spatial position of the operation site is measured into a fixed system of coordinates before or during the operation, and the measurement data are input to the data processing unit." (*Kliegis*, 2:64-3:2). Figure 1 of *Kliegis* shows the coordinate system (12). Additionally, *Kliegis* states that the "coordinate system (12) enables measurement of different anatomical relations of the patient." (*Id.*, 4:43-46). The only device described by *Kliegis* for use with the coordinate system is a scanner: "[a]n advantageous embodiment of the invention further includes a device for inputting coordinates, for example a scanner." (*Id.*, 4:27-30).



Therefore, the method disclosed in *Kliegis* describes the use of a video camera, or a coordinate system with a "scanner" to determine the position and orientation of the patient's body and of the incision path during a surgical procedure.¹

¹ *Kliegis* contains additional disclosure, which does not anticipate the claimed invention, regarding imaging taken prior to the surgical procedure to create a "three-dimensional desired image." *Kliegis* states that to plan and prepare for a surgical operation, a series of sectional images is produced with the aid of computed tomography and/or nuclear magnetic resonance tomography. The data determined by tomography is conveyed to DPU (1) where a three-dimensional desired image of said site is created from the measurement data. (*Kliegis*, 4:66-5:9). *Kliegis* goes on to state that the three-dimensional desired image is created from

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C. Kliegis Does Not Describe or Suggest the Claimed Invention

For anticipation under § 102, the reference must teach every aspect of the claimed invention. Also, the reference “must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation.” *See* MPEP § 2121.01. “A reference contains an ‘enabling disclosure’ if the public was in possession of the claimed invention before the date of the invention.” *Id.* Here, *Kliegis* does not anticipate the claimed invention because: (1) *Kliegis* does not teach every aspect of the claimed invention; and (2) because the disclosure that *Kliegis* does contain is not enabling to anticipate the claimed invention.

First, *Kliegis* does not disclose or suggest a method as described in independent claim 1 including the steps of:

- associating at least one first surgical reference with a portion of an individual’s bony anatomy and skin proximate the bony anatomy;
- registering the position and orientation of the portion of the individual’s bony anatomy and skin proximate the bony anatomy with the computer aided surgical navigation system such that the computer functionality can generate information corresponding to the position and orientation of the individual’s bony anatomy and skin proximate the bony anatomy by receiving information from the sensor sensing the position and orientation of the first surgical reference;

structural data that is obtained by evaluating computed tomography, nuclear magnetic resonance, ultrasound, X-ray, or holographic examinations. The three-dimensional (3-D) desired image makes it possible to plan the arrangement of the section surface of the operation site. (*Id.*, 2: 7-17). Therefore, *Kliegis* makes clear that the three-dimensional desired image is taken and prepared prior to the actual surgical procedure using tomography, for example. This portion of *Kliegis* does not describe or suggest a method that uses a CAS surgical reference or sensor.

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- associating at least one second surgical reference with an incision device, wherein the incision device is a cutting device or a marking device; or
- registering the position of the incision device with the computer aided surgical navigation system such that the computer functionality can generate information corresponding to the position of the incision device by receiving information from the sensor sensing the position and orientation of the second surgical reference.

Kliegis does not anticipate independent claim 1 because *Kliegis* does not describe or suggest each and every aspect of claim 1. Because *Kliegis* does not anticipate independent claim 1, then *Kliegis* likewise cannot anticipate dependent claims 2-9, which depend from claim 1.

Second, *Kliegis*'s disclosure is not enabling to anticipate the claimed invention. *Kliegis* merely discloses using a video camera and a "scanner" for a coordinate system to monitor the operation site during the surgical procedure, neither of which are enabling disclosure for a method that uses a CAS surgical reference or sensor. It would take undue experimentation to graduate from the video camera and "scanner" taught by *Kliegis* to the CAS surgical reference or sensor of the claimed invention.

The specification of the claimed invention describes some drawbacks of known methods that do not use CAS surgical reference or sensor and would be experienced by *Kliegis*. For example, some known methods "do not use the computer assisted surgical navigation system to track the progress of the surgical instrument during the surgical procedure. Consequently ... the surgeon may receive inaccurate guidance such that the incision is not performed along the desired incision path and / or length." (Specification, p. 4, l. 26 – p. 5, l. 6). Using a video camera during surgery would result in such inaccurate guidance. For example, if the patient's body moved during surgery, a video camera could not tell the surgeon the new position and orientation of the incision path. In contrast, in some embodiments of the claimed invention, "computer functionality 18 may be adapted to update the suggested incision path and length in real time if the position or orientation of the body part 36 changes. By tracking the position and orientation of the surgical reference or

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references 16 associated with the bony anatomy 42 and proximate skin 44 the computer functionality 18 may adjust the suggested incision path and / or length to compensate for changes in position and / or orientation of the body part 36." (Specification, p. 18, ll 1-6).

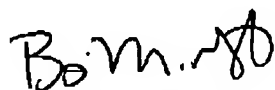
In conclusion, *Kliegis* does not describe or suggest all the elements of the claimed invention; and the teachings of *Kliegis* are not enabling to teach the claimed invention.

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CONCLUSION

After entry of the present amendment, the pending claims are 1-9. For at least the above reasons, Assignee respectfully requests that a timely Notice of Allowance be issued in this case. No fee is believed due; however, the Commissioner is hereby authorized to charge any fee that may be required to Deposit Account No. 11-0855. If there remain any additional issues to be addressed, the Examiner is invited to contact the undersigned attorney at 404-532-6965.

Respectfully submitted,



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